Cosmetic Act (the act) (21 U.S.C. 360aa(a)) and to designate such drug as a drug for a rare disease or condition under section 526(a) of the act (21 U.S.C. 360bb(a)).

(2) To issue holders of approved applications or licenses notice and opportunity for the submission of views under section 527(b)(1) of the act (921 U.S.C. 360cc(b)(1)).

(3) To encourage sponsors of an investigational new drug for a rare disease or condition to design protocols for clinical investigations to permit the addition to the investigation of persons with the disease or condition under section 528 of the act (21 U.S.C. 360dd).

(c) The following officials are authorized to provide sponsors, under section 525(a) of the act (21 U.S.C. 360aa(a)), with recommendations for nonclinical or clinical investigations believed to be necessary for a drug for a rare disease or condition to be approved or licensed:

(1) For drugs under their jurisdiction:

(i) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2) For biological products under their jurisdiction:

(i) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(ii) The Directors and Deputy Directors, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVRR), Office of Therapeutics Research and Review (OTRR), CBER.

(iii) The Directors and Deputy Directors of the Divisions in OBRR, OVRR, and OTRR, CBER.

(d) These officials may not further redelegate these authorities.

Subpart L—Mammography Facilities; Redelegations of Authority

§ 5.1000 Authority to ensure that mammography facilities meet quality standards.

(a) The following officials are authorized to ensure mammography facilities obtain certificates under section 354(b) of the Public Health Service Act (the PHS Act) (42 U.S.C. 263b(b)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Health and Industry Programs (OHIP), CDRH.

(3) The Director and Deputy Director, Division of Mammography Quality and Radiation Programs (DMQRP), OHIP, CDRH.

(b) The following officials are authorized to issue, renew and extend certificates to mammography facilities under section 354(c) of the PHS Act (42 U.S.C. 263b(c)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(c) The following officials are authorized to accept an application for a certificate under section 354(d)(1) of the PHS Act (42 U.S.C. 263b(d)(1)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(d) The following officials are authorized to approve accreditation bodies to accredit mammography facilities under section 354(e)(1)(A) of the PHS Act (42 U.S.C. 263b(e)(1)(A)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(e) The following officials are authorized to ensure accreditation bodies provide satisfactory assurances of compliance under section 354(e)(1)(C) of the PHS Act (42 U.S.C. 263b(e)(1)(c)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(f) The Director, CDRH is authorized to issue regulations under which the Director may withdraw approval of accreditation bodies under section 354(e)(2)(A) of the PHS Act (42 U.S.C. 263b(e)(2)(A)).

(g) The following officials are authorized to determine the expiration date of a certificate of a facility accredited by an accreditation body after the body's approval is withdrawn, or a State's certification authority has been withdrawn, or a facility's accreditation has been revoked by an accreditation body under sections 354(e)(2)(B) and 354(e)(5) of the PHS Act (42 U.S.C. 263b(e)(2)(B) and (e)(5)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(h) The following officials are authorized to determine the applicable standards for a facility for accreditation under section 354(e)(3) of the PHS Act (42 U.S.C. 263b(e)(3)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(i) The following officials are authorized to ensure accreditation bodies make on site visits and to determine whether other measures are appropriate under section 354(e)(4) of the PHS Act (42 U.S.C. 263b(e)(4)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(j) The following officials are authorized to evaluate annually the performance of each approved accreditation body as provided by section 354(e)(6)(A) of the PHS Act (41 U.S.C. 263b(e)(6)(A)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(k) The following officials are authorized to determine the compliance of certified facilities with established standards through annual facility inspections as provided by section 354(g) of the PHS Act (42 U.S.C. 263b(g)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(l) The following officials are authorized to promote voluntary compliance with established standards instead of taking actions under section 354(i) of the PHS Act (42 U.S.C. 263b(i)) by imposing directed plans of correction and/or payment of the cost of onsite monitoring under section 354(h)(1) of the PHS Act (42 U.S.C. 263b(h)(l)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(m) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH are authorized to impose sanctions under section 354(h)(2) of the PHS Act (42 U.S.C. 263b(h)(2)).

(n) The following officials are authorized to develop and implement the procedures for determining when and how to impose sanctions as provided by section 354(h)(3) of the PHS Act (42 U.S.C. 263b(h)(3)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(o) The following officials are authorized to suspend or revoke individual facility certificates under section 354(i)(1) and (i)(2) of the PHS Act (42 U.S.C. 263b(i)(1) and (i)(2)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(p) The following officials are authorized under section 354(i)(3) of the PHS Act (42 U.S.C. 263b(i)(3)) to ensure that no person who owned or operated a facility at the time the cause of revocation occurred may, within 2 years of the revocation of the certificate, own or operate a mammography facility:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(q) The following officials are authorized to compile and make available to physicians and the general public information determined to be useful in evaluating the performance of mammography facilities as provided by section 354(l) of the PHS Act (42 U.S.C. 263b(l):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(r) The following officials are authorized to ensure that appropriate Federal agencies are consulted in the development of standards, regulations, evaluations, procedures for compliance and oversight as provided by section 354(o) of the PHS Act (42 U.S.C. 263b(o)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(s) The following officials may authorize a State to carry out certification program requirements and implement quality standards under sections 354(q)(1) and (q)(2) of the PHS Act (42 U.S.C. 263b(g)(1) and (g)(2)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(t) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH are authorized, after providing notice and opportunity for corrective action, to withdraw the approval of a State's authority to carry out certification requirements and implement quality standards under section 354(q)(4) of the PHS Act (42 U.S.C. 263b(g)(4)).

(u) These officials may not further redelegate these authorities.

Subpart M—Organization

§ 5.1100 Headquarters.

The central organization of the Food and Drug Administration consists of the following:

OFFICE OF THE COMMISSIONER.[1]

Office of the Chief Counsel.

Office of Equal Opportunity.

Office of the Administrative Law Judge.

Office of the Senior Associate Commissioner.

Office of Executive Secretariat.

Office of Public Affairs.

Office of the Ombudsman.

Office of Orphan Products Development.

Office of Internal Affairs.

Office of Executive Operations.

Office of Science Coordination and Communication.

Office of Human Research Trials.

Office of International and Constituent Relations.

Office of International Programs.

Office of Consumer Affairs.

Office of Women's Health.

Office of Special Health Issues.

Office of Policy, Planning, and Legislation.

Office of Policy.

[1] Mailing address: 5600 Fishers Lane, Rockville, MD 20857.